



General Assembly

January Session, 2005

Raised Bill No. 6946

LCO No. 4508

04508_____PH_

Referred to Committee on Public Health

Introduced by:
(PH)

AN ACT ENSURING THE SAFETY OF MEDICINE.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. (NEW) (*Effective October 1, 2005*) As used in sections 1 to 7,
2 inclusive, of this act:

3 (1) "Authenticate" means to affirmatively verify, before any
4 distribution of a prescription drug occurs, that each transaction listed
5 on the pedigree has occurred.

6 (2) "Commission" means the Commission of Pharmacy.

7 (3) "Facility" means a facility of a wholesale distributor where
8 prescription drugs are stored, handled, repackaged or offered for sale.

9 (4) "Immediate family" means a dependent relative who resides in
10 the individual's household or any spouse, child or parent of the
11 individual.

12 (5) "Normal distribution channel" means a chain of custody for a
13 medication that goes from a manufacturer to a wholesaler to a
14 pharmacy to a patient.

15 (6) "Pedigree" means a document or electronic file containing
16 information that records each distribution of any given prescription
17 drug, from sale by a pharmaceutical manufacturer, through acquisition
18 and sale by any wholesale distributor or repackager, until final sale to
19 a pharmacy or other person dispensing or administering the
20 prescription drug.

21 (7) "Prescription drug" means any drug, including any biological
22 product, except for blood and blood components intended for
23 transfusion or biological products that are also medical devices
24 required by federal law or regulations, to be dispensed only by a
25 prescription, including finished dosage forms and bulk drug
26 substances subject to Section 503(b) of the federal Food, Drug and
27 Cosmetic Act.

28 (8) "Repackage" means repackaging or otherwise changing the
29 container, wrapper or labeling to further the distribution of a
30 prescription drug.

31 (9) "Repackager" means a person who repackages.

32 (10) "Wholesale distributor" means any person engaged in the
33 wholesale distribution of prescription drugs, including, but not limited
34 to, manufacturers, unless specified otherwise, repackagers, own-label
35 distributors, private-label distributors, jobbers, brokers, warehouses,
36 including manufacturers' and distributors' warehouses, chain drug
37 warehouses and wholesale drug warehouses, independent wholesale
38 drug traders and retail pharmacies that conduct wholesale
39 distribution.

40 Sec. 2. (NEW) (*Effective October 1, 2005*) Every wholesale distributor
41 that engages in the wholesale distribution of prescription drugs in the
42 state, including nonresident wholesale distributors that ship
43 prescription drugs into the state, shall be licensed by the commission,
44 in accordance with the provisions of sections 1 to 7, inclusive, of this
45 act, before engaging in the wholesale distribution of prescription drugs

46 in the state.

47 Sec. 3. (NEW) (*Effective October 1, 2005*) (a) Any person may apply to
48 the commission for a wholesale distributor license or for renewal of a
49 wholesale distributor license.

50 (b) The applicant shall disclose on the application (1) the name, full
51 business address and telephone number of the applicant or licensee;
52 (2) all trade or business names used by the applicant or licensee; (3)
53 addresses, telephone numbers and names of contact persons for all
54 facilities used by the applicant or licensee for the storage, handling and
55 distribution of prescription drugs; (4) the type of ownership or
56 operation, including, but not limited to, partnership, corporation or
57 sole proprietorship; (5) the name or names of the owner or operator of
58 the applicant or licensee and related information, including (A) if an
59 individual, the name of the individual, (B) if a partnership, the name of
60 each partner and the name of the partnership, (C) if a corporation, the
61 name and title of each corporate officer and director, the corporate
62 names and the state of incorporation, and (D) if a sole proprietorship,
63 the full name of the sole proprietor and the name of the business
64 entity; (6) a list of all licenses and permits issued to the applicant or
65 licensee by any other state that authorizes the applicant or licensee to
66 purchase or possess prescription drugs; (7) the name of the manager of
67 the facility that is applying for the initial license or to renew the
68 license, the next four highest ranking employees responsible for
69 prescription drug wholesale operations for the facility, and the name
70 of all affiliated parties for the facility, together with the personal
71 information statement required pursuant to subdivision (9) of this
72 subsection; (8) the name of the designated representative of the
73 applicant or licensee for the facility, together with the personal
74 information statement required pursuant to subdivision (9) of this
75 subsection and fingerprints for each such person; and (9) the following
76 information for each person described in subdivisions (7) and (8) of
77 this subsection who is required to provide a personal information
78 statement:

79 (A) The person's places of residence for the past seven years;

80 (B) The person's date and place of birth;

81 (C) The person's occupations, positions of employment and offices
82 held during the past seven years;

83 (D) The principal business and address of any business, corporation
84 or other organization in which each such office of the person was held
85 or in which each such occupation or position of employment was held;

86 (E) Whether the person was, during the past seven years, the subject
87 of any proceeding for the revocation of any license and, if so, the
88 nature and disposition of the proceeding;

89 (F) Whether, during the past seven years, the person was enjoined,
90 either temporarily or permanently, by a court of competent jurisdiction
91 from violating any federal or state law regulating the possession,
92 control or distribution of prescription drugs, together with details
93 concerning any such event;

94 (G) A description of any involvement by the person with any
95 business, including any investments, other than the ownership of stock
96 in a publicly traded company or mutual fund, during the past seven
97 years, that manufactured, administered, prescribed, distributed or
98 stored pharmaceutical products and any lawsuits in which such
99 business was named as a party;

100 (H) A description of any felony criminal offense of which the
101 person, as an adult, was found guilty, regardless of whether
102 adjudication of guilt was withheld or whether the person pled guilty
103 or nolo contendere. If the person indicates that a criminal conviction is
104 under appeal and submits a copy of the notice of appeal of that
105 criminal offense, the applicant or licensee shall, not later than fifteen
106 days after the disposition of the appeal, submit to the state a copy of
107 the final written order of disposition; and

108 (I) A photograph of the person taken not earlier than the thirty-day
109 period preceding submission to the commission of the information
110 required by this subsection.

111 (c) The commission shall not issue or renew a wholesale distributor
112 license unless the commission determines that the applicant's
113 designated representative meets all of the following qualifications: (1)
114 Is at least twenty-one years of age; (2) has been employed full time for
115 at least three years in a pharmacy or with a wholesale distributor in a
116 capacity related to the dispensing and distribution of and
117 recordkeeping relating to prescription drugs; (3) has received a score
118 of seventy-five per cent or more on an examination given by the
119 commission regarding federal and state laws governing wholesale
120 distribution of prescription drugs, provided a designated
121 representative who previously served in such capacity retakes the state
122 examination each time a licensee lists the person as the designated
123 representative in an application for license renewal; (4) is employed by
124 the applicant full time in a managerial position; (5) is actively involved
125 in and aware of the actual daily operation of the wholesale distributor;
126 (6) is physically present at the applicant's facility during regular
127 business hours, except when the absence of the designated
128 representative is authorized, including, but not limited to, absences
129 due to sick leave or vacation leave; (7) is serving in the capacity of a
130 designated representative for only one applicant or licensee at a time;
131 (8) does not have any convictions under any federal, state or local laws
132 relating to wholesale or retail prescription drug distribution or
133 distribution of controlled substances; and (9) does not have any felony
134 convictions under federal, state, or local laws.

135 (d) The applicant shall submit to a criminal history records check in
136 accordance with the provisions of section 29-17a of the general
137 statutes.

138 (e) The commission shall require each applicant to submit a bond in
139 an amount determined by the commission or other equivalent means

140 of security acceptable to the commission, such as an irrevocable letter
141 of credit or a deposit in a trust account or financial institution, payable
142 to the drug wholesaler account established pursuant to section 8 of this
143 act. The purpose of the bond is to secure payment of any fines or
144 penalties imposed by the commission and any fees or costs incurred by
145 the commission regarding a wholesale distributor license under the
146 provisions of sections 1 to 7, inclusive, of this act and which the
147 licensee fails to pay by the date thirty days after the date such fines,
148 penalties, fees or costs become final. The commission may make a
149 claim against such bond or security up to one year after the date the
150 licensee's license ceases to be valid.

151 (f) If a wholesale distributor distributes prescription drugs from
152 more than one facility, the wholesale distributor shall obtain a
153 wholesale distributor license for each facility.

154 (g) A wholesale distributor licensed pursuant to the provisions of
155 sections 1 to 7, inclusive, of this act shall notify the commission of any
156 changes to the information required in subsection (b) of this section not
157 later than thirty days after such change.

158 Sec. 4. (NEW) (*Effective October 1, 2005*) (a) On and after October 1,
159 2005, in any calendar month, a wholesale distributor shall sell,
160 distribute, transfer or otherwise sell at least ninety-five per cent of its
161 total amount of prescription drugs to a pharmacy or other person
162 dispensing or administering the drug.

163 (b) A wholesale distributor shall not purchase or otherwise receive a
164 prescription drug from a pharmacy, except that a wholesale distributor
165 may receive a prescription drug from a pharmacy if the prescription
166 drug was originally purchased by the pharmacy from the wholesale
167 distributor.

168 (c) A wholesale distributor that meets the exception in subsection
169 (b) of this section shall not: (1) Receive from a pharmacy an amount or
170 quantity of a prescription drug larger than the amount or quantity that

171 was originally sold by the wholesale distributor to the pharmacy; or (2)
172 pay the pharmacy an amount, either in cash or credit, more than the
173 pharmacy originally paid the wholesale distributor for the prescription
174 drug.

175 (d) A manufacturer or wholesale distributor shall furnish
176 prescription drugs only to a person licensed by the appropriate state
177 licensing authorities. Before furnishing prescription drugs to a person
178 not known to the manufacturer or wholesale distributor, the
179 manufacturer or wholesale distributor shall affirmatively verify the
180 person is legally authorized to receive the prescription drugs by
181 contacting the appropriate state licensing authorities.

182 (e) Prescription drugs furnished by a manufacturer or wholesale
183 distributor shall be delivered only to the premises listed on the license,
184 provided the manufacturer or wholesale distributor may furnish
185 prescription drugs to an authorized person or agent of that person at
186 the premises of the manufacturer or wholesale distributor if: (1) The
187 identity and authorization of the recipient is properly established; and
188 (2) this method of receipt is employed only to meet the immediate
189 needs of a particular patient of the authorized person. Prescription
190 drugs may be furnished to a hospital pharmacy receiving area,
191 provided a pharmacist or authorized receiving personnel signs, at the
192 time of delivery, a receipt stating the type and quantity of such
193 prescription drug or drugs received. Any discrepancy between the
194 receipt and the type and quantity of the prescription drug actually
195 received shall be reported to the delivering manufacturer or wholesale
196 distributor on or before the next business day after delivery to the
197 pharmacy receiving area.

198 (f) A manufacturer or wholesale distributor shall not accept
199 payment for, or allow the use of, a person or entity's credit to establish
200 an account for the purchase of prescription drugs from any person
201 other than the owner or owners of record, the chief executive officer or
202 the chief financial officer listed on the license of a person or entity

203 legally authorized to receive prescription drugs. Any account
204 established for the purchase of prescription drugs shall bear the name
205 of the licensee.

206 Sec. 5. (NEW) (*Effective October 1, 2005*) (a) Each person who is
207 engaged in the wholesale distribution of a prescription drug, including
208 repackagers, but excluding the original manufacturer of the finished
209 form of the prescription drug, shall provide a pedigree or electronic
210 file identifying each sale, trade or transfer of a prescription drug when
211 a prescription drug leaves the normal distribution channel and is sold,
212 traded or transferred to any other person. If a pharmacy sells a drug to
213 any person who is not the final consumer, the pharmacy shall provide
214 to the person acquiring the prescription drug a pedigree identifying
215 each sale, trade or transfer of a prescription drug. This subsection shall
216 not be construed to apply to the sale, trade or transfer of a prescription
217 drug between licensees with a common ownership or to meet
218 emergency needs.

219 (b) Each person who is engaged in the wholesale distribution of a
220 prescription drug, including repackagers, but excluding the original
221 manufacture of the finished form of the prescription drug, who is in
222 possession of a pedigree for a prescription drug and attempts to
223 further distribute such prescription drug, shall affirmatively verify
224 before any distribution of a prescription drug occurs that each
225 transaction listed on the pedigree has occurred.

226 (c) The pedigree shall:

227 (1) Include all necessary identifying information concerning each
228 sale in the chain of distribution of the product from the manufacture,
229 through acquisition and sale by any wholesale distributor or
230 repackager, until final sale to a pharmacy or other person dispensing
231 or administering the drug. The necessary chain of distribution
232 information shall include, but shall not be limited to: (A) The name,
233 address, telephone number and, if available, the electronic mail
234 address, of each owner of the prescription drug and each wholesale

235 distributor who does not take title to the prescription drug; (B) the
236 signature of each owner of the prescription drug and each wholesale
237 distributor who does not take title to the prescription drug; (C) the
238 name and address of each location from which the product was
239 shipped, if different from the owner's; (D) the transaction dates; and
240 (E) certification that each recipient has authenticated the pedigree.

241 (2) The pedigree shall also include, but shall not be limited to: (A)
242 The name of the prescription drug; (B) dosage form and strength of the
243 prescription drug; (C) size of the container; (D) number of containers;
244 (E) lot number of the prescription drug; and (F) name of the
245 manufacturer of the finished dosage form.

246 (d) Each pedigree shall be: (1) Maintained by the purchaser and the
247 wholesale distributor for three years; and (2) available for inspection or
248 removal upon request of an authorized officer of the law.

249 (e) The Commissioner of Consumer Protection, with the advice and
250 assistance of the Commission of Pharmacy, shall adopt regulations, in
251 accordance with chapter 54 of the general statutes, to carry out the
252 provisions of this section.

253 Sec. 6. (NEW) (*Effective October 1, 2005*) (a) If the state finds that
254 there is a reasonable probability that: (1) A wholesale distributor has:
255 (A) Knowingly violated a provision of sections 1 to 7, inclusive, of this
256 act; or (B) falsified a pedigree, or knowingly sold, distributed,
257 transferred, manufactured, repackaged, handled or held a counterfeit
258 prescription drug intended for human use; (2) the prescription drug
259 that is alleged to be in violation of subdivision (1) of this subsection
260 could cause serious adverse health consequences or death; and (3)
261 other procedures would result in unreasonable delay, the state shall
262 issue an order requiring the appropriate person, including the
263 manufacturers, distributors or retailers of the drug, to immediately
264 cease distribution of the drug.

265 (b) An order issued under subdivision (3) of subsection (a) of this

266 section shall provide the person subject to the order with an
267 opportunity for an informal hearing, to be held not later than ten days
268 after the date of the issuance of the order, on the actions required by
269 the order. If, after providing an opportunity for such a hearing, the
270 state determines that inadequate grounds exist to support the actions
271 required by the order, the state shall vacate the order.

272 Sec. 7. (NEW) (*Effective October 1, 2005*) (a) It shall be unlawful for a
273 person to perform or cause the performance of or aid and abet any of
274 the following acts in this state:

275 (1) Failure to obtain a license in accordance with sections 1 to 7,
276 inclusive, of this act, or operating without a valid license when a
277 license is required by sections 1 to 7, inclusive, of this act;

278 (2) Selling, distributing, transferring or otherwise providing
279 prescription drugs in violation of the five per cent rule established in
280 subsection (a) of section 4 of this act;

281 (3) Purchasing or otherwise receiving a prescription drug from a
282 pharmacy in violation of the provisions of subsection (b) or (c) of
283 section 4 of this act;

284 (4) The sale, distribution or transfer of a prescription drug to a
285 person that is not authorized under the law of the jurisdiction in which
286 the person receives the prescription drug to receive the prescription
287 drug, in violation of subsection (d) of section 4 of this act;

288 (5) Failure to deliver prescription drugs to specified premises, in
289 accordance with the provisions of subsection (e) of section 4 of this act;

290 (6) Accepting payment or credit for the sale of prescription drugs, in
291 violation of subsection (f) of section 4 of this act;

292 (7) Failure to maintain or provide pedigrees, in accordance with the
293 provisions of section 5 of this act;

294 (8) Failure to obtain, pass or authenticate a pedigree, in violation of
295 section 5 of this act;

296 (9) Providing the state or any of its representatives or any federal
297 official with false or fraudulent records or making false or fraudulent
298 statements regarding any matter under the provisions of sections 1 to
299 7, inclusive, of this act;

300 (10) Obtaining or attempting to obtain a prescription drug by fraud,
301 deceit, misrepresentation or engaging in misrepresentation or fraud in
302 the distribution of a prescription drug;

303 (11) The manufacture, repacking, sale, transfer, delivery, holding or
304 offering for sale any prescription drug that is adulterated, misbranded,
305 counterfeit, suspected of being counterfeit or has otherwise been
306 rendered unfit for distribution;

307 (12) The adulteration, misbranding or counterfeiting of any
308 prescription drug;

309 (13) The receipt of any prescription drug that is knowingly
310 adulterated, misbranded, stolen, obtained by fraud or deceit,
311 counterfeit or suspected of being counterfeit and the delivery or
312 proffered delivery of such drug for pay or otherwise; and

313 (14) The alteration, mutilation, destruction, obliteration or removal
314 of the whole or any part of the labeling of a prescription drug or the
315 commission of any other act with respect to a prescription drug that
316 results in the prescription drug being misbranded.

317 (b) Any person who violates the provisions of subsection (a) of this
318 section shall be fined not more than twenty thousand dollars or
319 imprisoned not less than ten years or more than twenty-five years, or
320 both.

321 Sec. 8. (NEW) (*Effective July 1, 2005*) There is established a drug
322 wholesaler account which shall be a separate, nonlapsing account

323 within the General Fund. The account may contain proceeds from the
324 bond prescribed by subsection (e) of section 3 of this act and any other
325 moneys required by law to be deposited in the account, and shall be
326 held in trust separate and apart from all other moneys, funds and
327 accounts. Any balance remaining in the account at the end of any fiscal
328 year shall be carried forward in the account for the fiscal year next
329 succeeding. Investment earnings credited to the account shall become
330 part of the account. Amounts in the account shall be expended only
331 pursuant to appropriations by the General Assembly, for the fiscal
332 year ending June 30, 2006, and each fiscal year thereafter, for the
333 purposes prescribed in subsection (e) of section 3 of this act, provided
334 such amounts so expended shall not supplant any state or federal
335 funds otherwise available for such services.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>October 1, 2005</i>	New section
Sec. 2	<i>October 1, 2005</i>	New section
Sec. 3	<i>October 1, 2005</i>	New section
Sec. 4	<i>October 1, 2005</i>	New section
Sec. 5	<i>October 1, 2005</i>	New section
Sec. 6	<i>October 1, 2005</i>	New section
Sec. 7	<i>October 1, 2005</i>	New section
Sec. 8	<i>July 1, 2005</i>	New section

Statement of Purpose:

To require the licensing of wholesale prescription drug distributors to prevent counterfeit drugs from reaching consumers.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]